IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C. R. BARD, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL NO.: 2187**
THIS DOCUMENT RELATES TO:	
DONNA CISSON and DAN CISSON	**2:11-cv-00195**

PLAINTIFFS' MOTION IN LIMINE NO. 1 - 510(K) CLEARANCE OF THE AVAULTA PRODUCTS BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION ("FDA"), OR LACK OF FDA ENFORCEMENT ACTION

Plaintiffs respectfully move the Court to preclude any defense argument or introduction of evidence or testimony relating to the FDA's 510(k) clearance of the Avaulta products, or the lack of FDA enforcement action relative to the Avaulta products, for the reasons and based on the authority cited below.

Bard should not be allowed to mislead and confuse the jury and prejudice the Plaintiffs by introducing evidence of the FDA's 510(k) clearance of the Avaulta products, and lack of enforcement action relative to the products. From its summary judgment motions and various other pleadings filed in this case, it is evident that Bard intends to rely on the FDA's 510(k) clearance to sell the Avaulta products, and the fact that the FDA never took any enforcement action relative to the Avaulta products during their market lifespan, to support its contention that these products are safe and effective.[1]

[1] Bard Summary Judgment Brief, Statement of Material Facts, Section C ("*The FDA cleared Bard's Avaulta Systems for marketing in the United States, and the FDA never took enforcement action against Bard.*"; "*Congress has granted the FDA the authority to regulate medical devices, which are heavily scrutinized by the FDA both before and after they are placed on the market.*"; "*In the course of Bard's submissions to the FDA, the FDA never informed Bard that the labeling or design for the Avaulta Systems was not satisfactory. Furthermore, the FDA never took any enforcement actions against Bard in relation to the Avaulta Systems.*"); Bard Punitive Damages Summary Judgment Brief, Introduction ("*All of Bard's actions concerning the Avaulta Systems – development, manufacture, marketing, etc. –…adhered to the*

The FDA's 510(k) process by which the Avaulta products were cleared for sale does not determine – indeed does not relate to – product safety or effectiveness. The FDA's 510(k) clearance process (in general and specific to Avaulta), and the FDA's lack of enforcement action relative to Avaulta, are simply irrelevant. Even it were assumed *arguendo* that such evidence would have a tendency to make any consequential fact more or less probable, however, any alleged probative value would be substantially outweighed by the numerous dangers associated with admission of such evidence and it should be excluded under Federal Rule of Evidence 403.

A. Any evidence relating to the FDA's clearance of the Avaulta products, and the lack of FDA enforcement action, should be excluded as irrelevant and immaterial.

Bard has argued to date that because the FDA cleared the Avaulta products through the 510(k) process and never took any enforcement action against the products, the products were safe and effective, and its warnings were adequate. Bard's argument is inaccurate and misleading. The issues of consequence in this case involve the alleged defectiveness of the Avaulta products in their manufacture, design and/or warnings, and whether the products were a cause of the Plaintiffs' injuries. The fact that the FDA cleared the Avaulta products for sale, and never took enforcement action relative to Avaulta devices, makes no such issue more or less probable.

The Avaulta products were "cleared" through the FDA's 510(k) "pre-market notification" process, under which products are allowed to be marketed based on a finding of "substantial equivalence" to a product on the market prior to 1976, rather than a determination of the product's safety or efficacy. The FDA itself explained the difference between the 510(k) process

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extensive federal regulatory scheme imposed by the…FDA."); Bard Punitive Damages Summary Judgment Reply Brief, Section IV ("*Despite Plaintiffs' erroneous assertions to the contrary, the 510(k) process does address safety and efficacy.*"); Bard Punitive Damages Summary Judgment Reply Brief, Argument, Section I.B. ("*Despite this extensive regulatory oversight,…the FDA never took any enforcement actions against Bard in relation to its Avaulta product line.*").

and the more rigorous "premarket approval" process in an amicus brief filed with the 3rd Circuit in Horn v. Thoratec Corp., 376 F.3d 163, 167 (3d Cir.2004), recited in the opinion as follows:

> A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with Section 510(k)…. A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). *A pre-market notification submitted under 510(k) is thus entirely different from a* [premarket approval,] *which must include data sufficient to demonstrate that the device is safe and effective*. (Emphasis in original).

In Medtronic, Inc. v. Lohr, 518 U.S. 470, 478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…. The § 510(k) notification process is by no means comparable to the [premarket approval] process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours…. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.[2]

In rejecting the manufacturer's contention that the 510(k) process amounted to a specific federal design requirement, the Supreme Court in Lohr stated "**The [defendant] exaggerates the importance of the 510(k) process**….**the 510(k) process is focused on *equivalence*, not safety. As a result, substantial equivalence determinations provide little protection to the public…. [T]he design of…'substantially equivalent' devices has never been formally reviewed…for safety or efficacy**." Id. at 493 (Emphasis added); See also, Riegel v. Medtronic, Inc., 552 U.S. 312, 323 (2008) ("While § 510(k) is focused on *equivalence*, not safety, premarket approval is focused on safety, not equivalence.").[3] Thus, Bard's argument that the FDA considered or

[2] The Supreme Court's accurate depiction of the 510(k) process in Lohr refutes Bard's repeated contention that the products were "heavily scrutinized," or that the 510(k) process is "extensive."

[3] Insofar as Bard's repeated assertion that the FDA never took any enforcement action, that too was addressed in Lohr where the Court noted that "[t]he FDA's authority to require manufacturers to recall,

determined in the 510(k) process whether the Avaulta products is "safe and effective"[4] is improper and misleading – as the Supreme Court explained in Lohr, the FDA never formally reviewed or considered the safety or efficacy of the Avaulta products during the 510(k) process. For Bard to even suggest that the 510(k) process determined the safety and efficacy of the Avaulta products contravenes the FDA's regulations, which outright prohibit a device manufacturer from making "**any representation that creates an impression of official approval of a [510(k)] device**" because any such representation is "**misleading**." 21 C.F.R. § 807.97.

Any argument that Bard's compliance with the FDA's regulatory scheme bears on the reasonableness of its conduct, or on the safety of the Avaulta products, would be without merit. Some courts hold that a manufacturer's compliance with federal safety standards and requirements can be admitted in a product liability action under certain circumstances for certain limited purposes, although such evidence has no binding or preclusive effect – compliance with such federal safety standards is said to establish a "floor," rather than a ceiling. See, e.g., Dorsey v. Honda Motor Co., Ltd., 655 F.2d 650, 656 (5th Cir.1981); Ake v. Gen. Motors Corp., 942 F.Supp. 869, 873-74 (W.D.N.Y.1996); Stonehocker v. Gen. Motors Corp., 587 F.2d 151, 156-57 (4th Cir. 1978).[5] However, the rationale for admission of such evidence disappears where, as in

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replace, or refund defective devices is of little use to injured plaintiffs, since there is no indication that the right is available to private parties, the remedy would not extend to recovery for compensatory damages, and the authority is rarely invoked, if at all." 518 U.S. at 487 n. 7.

[4] See, Bard's Punitive Damages Summary Judgment Brief, Argument, Section IV ("Despite Plaintiffs' erroneous assertions to the contrary, the 510(k) process does address safety and efficacy."; "Plaintiffs' attempt to posit that there are no regulations to establish the safety of a 510(k) device is simply incorrect.").

[5] For example, as in Dorsey, Ake and Stonehocker, courts have allowed auto manufacturers to prove compliance with federal motor vehicle safety standards ("FMVSS") which establish substantive minimum safety requirements (such as steering wheel displacement; seat assembly strength; seat belt strength and elasticity; fuel tank vulnerability; roof crush strength, etc.) because they bear on the reasonableness of the

this case, there are no substantive standards or requirements that relate to product safety or design.

As the Supreme Court made clear in Lohr, supra at 471 and reiterated in Riegel v. Medtronic, Inc., 552 U.S. 312, 322 (2008), the 510(k) process does not establish or impose any specific requirements, and there are otherwise no federal specifications or standards that relate to the safety or design of the Avaulta products. In Talley v. Danek Medical, Inc., 179 F.3d 154, 161 (4th Cir.1999), the Fourth Circuit explained that the FDA's requirement that a Class III device must obtain FDA pre-market approval before it can be marketed "is only a tool to facilitate administration of the underlying regulatory scheme. Because it lacks any independent substantive content, it does not impose a standard of care…. It is analogous to the failure to have a drivers license." Under this reasoning, a manufacturer's purported compliance with the FDA's regulatory scheme does not constitute evidence of ordinary care – it would be akin to a defendant in a car wreck case defending herself based on the fact that she was licensed by the State to drive. The reasoning in Talley applies *a fortiori* in the context of a 510(k) device, which unlike the premarket approval process for Class III devices, has no relation to product safety. The 510(k) process unquestionably "lacks any independent substantive content" in terms of device safety or design, and compliance with any 510(k) regulations is thus irrelevant to Bard's duty of care or the safety of its products. Any evidence of Bard's compliance with any FDA regulations

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manufacturer's conduct. See also, DePaepe v. Gen. Motors Corp., 141 F.3d 715, 718 (7th Cir. 1998) (explaining that FMVSS contain design standards, which specify what a vehicle component must be (ex.: every car must have seatbelts); or performance standards, which describe what the component must accomplish (ex.: a safety belt anchorage must withstand 5,000 lb. force)). Other courts have held that proof of compliance with substantive federal safety standards is irrelevant and inadmissible in a strict liability products case. Harsh v. Petroll, 840 A.2d 404, 424-25 (Pa. 2003); Malcolm v. Evenflo Co., Inc., 217 P.3d 514, 521-23 (Mont. 2009). The Court need not make that determination here because there are no federal safety standards – or any safety standards – at issue.

in connection with the Avaulta would prove nothing that would bear on any issue to be tried in this action; it is irrelevant.

Bard's assertions as to what should be implied (the Avaulta products must be safe) from the fact that the FDA did not undertake enforcement action relative to the Avaulta products are likewise immaterial and inadmissible. Evidence regarding the knowledge, motivations, intent, state of mind, or purposes of the FDA or FDA officials is inadmissible. See, e.g., In re Fosamax Prod. Liab. Litig., 645 F.Supp.2d 164, 192 (S.D.N.Y.2009). Any suggestion or insinuation as to why the FDA did not take enforcement action against Bard relative to the Avaulta products would impermissibly invite the jury to speculate as to what the FDA intended or what the agency or its employees were thinking.[6] Bard cannot validly attempt to convince the jury to infer anything with respect to the safety or efficacy of the Avaulta from the FDA's inaction or from its regulatory authority in general.

B. Any evidence relating to the FDA should be excluded under Federal Rule of Evidence 403.[7]

Even assuming for the purposes of argument only that the FDA's clearance of the Avaulta products under the 510(k) process or its failure to take enforcement action against Bard

[6] It could just as easily be argued that there was no recall because the FDA's post-market complaint monitoring system is fundamentally flawed, because adverse events are vastly underreported to the FDA, or because the FDA simply lacks adequate resources and proper statutory authority to validly monitor post-market adverse events. That is what David A. Kessler, M.D., former FDA Commissioner (and Plaintiffs' expert herein), explained in his 2008 article published in the Georgetown Law Journal, *A Critical Examination of the FDA's Efforts to Preempt Failure-To-Warn Claims*, 96 Geo. L.J. 461, 484-491 (2008). See also, Heckler v. Chaney, 470 U.S. 821, 831 (1985) (observing that agency enforcement action "involves a complicated balancing of a number of factors…."); Freightliner Corp. v. Myrick, 514 U.S. 280, 286 (1995) (rejecting manufacturer's argument that "the absence of regulation itself constitutes regulation."). The jury should not be burdened with deciding what hypothetically could have motivated the FDA's lack of recall because it is simply impossible to prove, and it is plainly not a proper legal inquiry.

[7] Rule 403 provides that "[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."

could be considered relevant to any issue in this litigation, it should nonetheless be excluded under Federal Rule of Evidence 403. Nearly every one of the individual Rule 403 factors weigh against any arguable probative value of FDA-related evidence, and the unfair prejudice inherent in such evidence substantially outweighs any asserted probative worth.

The Plaintiffs will be unfairly prejudiced[8] – and the jury will be misled and confused – by Bard's misleading suggestion that the FDA's 510(k) clearance determined that the Avaulta products were safe, and that the FDA's lack of enforcement action signifies that the products were safe. If Bard were allowed to rely on the FDA's clearance of the Avaulta or lack of FDA enforcement action, Plaintiffs would be forced to try and overcome the inaccurate insinuation. The prejudicial seed that would be planted by Bard's FDA "clearance" or lack-of-enforcement action argument would be exceedingly difficult for Plaintiffs to uproot.

In order to try and overcome the improper suggestion that the FDA has ever determined – or even considered – the safety of the Avaulta, Plaintiffs would be forced to divert their (and consequently the jury's) attention from the material issues by presenting expert testimony to explain the FDA's 510(k) process and what the FDA does and does not determine in that process. Being presented with such evidence, the jurors would likely be confused into believing that they have to determine the propriety of the FDA's conduct relative to the Avaulta products (whether or not the FDA should have cleared the products), or to understand the FDA's regulatory process as it relates to these products, in order to decide this case. The prejudice from this evidence would be exacerbated by the fact that Plaintiffs will have a limited time in which to present their case. By forcing Plaintiffs to address its irrelevant FDA clearance/lack of enforcement arguments, Bard will in essence put the FDA and its processes and conduct on trial,

[8] The Comments to Rule 403 provide that "'Unfair prejudice' within its context means an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one."

thereby distracting the jury's attention away from itself and its product. What should be a non-issue would become a focal point of the trial (as it has been in Bard's briefing to date). The danger of a jury being misled by evidence relating to the FDA's clearance of the Avaulta is reflected in the FDA's own regulations which provide that any representation creating even an *impression* of official approval would be "misleading." 21 C.F.R. § 807.97. Likewise, Bard's immaterial FDA clearance and lack of enforcement evidence will result in undue delay and will waste valuable time. Presenting evidence relating to the FDA process will take this case on a tangent far afield from the core issues to be decided, and the consequences of such a detour will be unfair prejudice to the Plaintiffs, a confused and misled jury, and an unwarranted and undue delay in the jury's consideration of the merits of the case.

The danger of unfair prejudice to Plaintiffs from evidence regarding the FDA's clearance of Avaulta and lack of enforcement action would be exponentially magnified by Bard's assertion that Plaintiffs are prohibited from challenging the sufficiency or accuracy of Bard's submissions to the FDA. (See, e.g., Bard's Brief in Support of its Kessler Daubert motion, Argument, Section C (urging that Dr. Kessler's testimony regarding information that was not provided to the FDA should be excluded)). Indeed, Bard has indicated in its Daubert briefing that it intends to move to exclude any evidence that Bard violated FDA regulations, misled the FDA, or withheld information from the FDA as inadmissible under Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 343 (2001). (Id., footnote 7). However, Bard turns around and argues that it has the right to introduce evidence regarding the propriety of its conduct in dealing with the FDA. (Bard Reply Brief in Support of its Kessler Daubert motion, Argument, Section III.C. ("[T]estimony asserting that Bard appropriately disclosed information to the FDA is consistent with the FDA's determination never to take an enforcement action against Bard with respect to its Avaulta

products.")). It would be unfairly prejudicial to allow Bard to argue that it did everything it was supposed to do, and that the FDA cleared the product and did not take enforcement action, but simultaneously move to preclude Plaintiffs from showing the jury that facts were withheld from or misrepresented to the FDA in Bard's 510(k) submission. The Court should not have to decide whether, or how far, Bard has opened the door to this evidence; it should leave the door closed to this irrelevant and prejudicial evidence altogether.

A similar motion was filed on behalf of the plaintiffs by the undersigned in the Mentor ObTape MDL prior to the initial trial in that litigation, and the Court there granted the motion, and excluded any reference to the FDA's 510(k) process for that trial. (See, copy of Minutes Sheet granting Plaintiffs' FDA motion in limine in Mentor (docket entry 249 in that case) attached hereto as "**Exhibit 1**"). The Court in Mentor held a hearing on the issue and explained its rationale in granting the motion. (An excerpt copy of the May 3, 2010 Mentor hearing transcript is attached hereto as "**Exhibit 2**"). As the Court discussed at length at the hearing in Mentor, the FDA's 510(k) process was simply not probative of any issue in that litigation.[9] Upon considering arguments from both sides, the Court concluded "I don't find [the FDA 510(k) clearance evidence] relevant. And I find that if it is relevant, that under Rule 403 it should be excluded because of the danger of unfair prejudice and confusion of the issues." (**Exhibit 2**, p. 174:9-12). Plaintiffs respectfully submit that a similar conclusion is warranted here, and that their motion should be granted. Bard should be precluded from making any reference to the FDA's 510(k) clearance of the Avaulta products, or to the alleged lack of enforcement action by the FDA relative to the Avaulta products.

[9] "[O]n the design and manufacturing defect, I don't see how the FDA's approval is relevant as to whether the design was defective or not." (**Exhibit 2**, p. 164:16-25); "I think what [Plaintiffs' counsel is] saying is that it's not an appropriate defense to [design defect] 'but the FDA let us do it.' And I agree with him." (Id., 167:25-168:2); "Just mere compliance with some law that's not relevant to the determination at trial means nothing." (Id., 170:4-6).

This 3rd day of June, 2013.

By: */s/ Henry G. Garrard, III*
Henry G. Garrard, III
hgg@bbgbalaw.com
Georgia Bar No. 286300
Gary B. Blasingame
gbb@bbgbalaw.com
Georgia Bar No. 062900
James B. Matthews, III
jbm@bbgbalaw.com
Georgia Bar No. 477559
Andrew J. Hill, III
ajh@bbgbalaw.com
Georgia Bar No. 353300
Josh B. Wages
jbw@bbgbalaw.com
Georgia Bar No. 730098
Counsel for the Plaintiffs

Blasingame, Burch, Garrard & Ashley, P.C.
P.O. Box 832
Athens, GA 30603
(706) 354-4000

CERTIFICATE OF SERVICE

I hereby certify that on June 3, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this M.D.L.

By: */s/ Henry G. Garrard, III*

Henry G. Garrard, III
hgg@bbgbalaw.com
Georgia Bar No. 286300
Gary B. Blasingame
gbb@bbgbalaw.com
Georgia Bar No. 062900
James B. Matthews, III
jbm@bbgbalaw.com
Georgia Bar No. 477559
Andrew J. Hill, III
ajh@bbgbalaw.com
Georgia Bar No. 353300
Josh B. Wages
jbw@bbgbalaw.com
Georgia Bar No. 730098
Counsel for the Plaintiffs

Blasingame, Burch, Garrard & Ashley, P.C.
P.O. Box 832
Athens, GA 30603
(706) 354-4000